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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/255,655	02/23/99	VIGH	M 02405.0167

HM22/1104  
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EXAMINER

OWENS JR, H

ART UNIT

PAPER NUMBER

1623

6

DATE MAILED: 11/04/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/255,655

Applicant(s)

Vigh et al.

Examiner

Howard Owens

Group Art Unit

1623



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

5 This application currently names joint inventors. In  
considering patentability of the claims under 35 U.S.C. 103(a),  
the examiner presumes that the subject matter of the various  
claims was commonly owned at the time any inventions covered  
therein were made absent any evidence to the contrary. Applicant  
is advised of the obligation under 37 CAR 1.56 to point out the  
10 inventor and invention dates of each claim that was not commonly  
owned at the time a later invention was made in order for the  
examiner to consider the applicability of 35 U.S.C. 103<sup>®</sup> and  
potential 35 U.S.C. 102(f) or (g) prior art under 35  
U.S.C. 103(a).

Drawings Objected to

20 The drawings are objected to, see the attached PTO-948.  
Correction is required.

Reference in 1.60 Continuing Applications

25 This application filed under 37 C.F.R. § 1.60 lacks the  
necessary reference to the prior application. A statement  
reading "This is a Continuation of provisional application No.  
30 60/075,694, filed 2/24/98" should be entered following the title  
of the invention or as the first sentence of the specification.

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35 U.S.C. § 103 REJECTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Zehner, U.S. Patent No. 4,786,722, in combination with Morelli, U.S. Patent No. 5,709,857, MacFarlane et al., The Large Intestine: Physiology, Pathophysiology and Disease, pp. 51-92, 1991 and Mortensen et al., American Institute of Nutrition, pp. 321-325.

Claims 1-6 are drawn to a method for inducing production of butyrate comprising administering D-tagatose.

Claims 7-12 are drawn to a method for stimulating the growth of lactobacilli and lactic acid bacteria comprising administering D-tagatose.

MacFarlane et al. teach that bacterial populations such as Lactobacilli grow on carbon sources supplied by substrates such as monosaccharides and disaccharides (pp. 52-56). MacFarlane et al. also teach that unabsorbed sugars and alcohols are substrates available for fermentation in the human colon wherein the byproducts are SCFA's such as butyrate and propionate (see table 4).

Mortensen et al. teach that a substantial capacity for enhancement of the Short Chain Fatty Acid (propionate and butyrate specifically) production is available when sufficient amounts of an appropriate substrate are present (p. 324,

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paragraphs 2) that substrate being monosaccharides such as hexoses, pentoses or uronic acid monomers (p. 322, lines 1-9). However, Mortensen does not specifically cite D-tagatose.

5       Zehner teaches that D-tagatose is slowly degraded by indigenous microflora such as *Lactobacillus casei* and is metabolized at a small extent by the body. Zehner also teaches that D-tagatose may serve as a bulking agent in foodstuffs, juices or other liquid preparations(col.2-col.3).

10       Morelli teaches that several species of *Lactobacillus* positively ferment carbohydrates such as Tagatose, see tables 3 and 4.

15       Mortensen et al. and Macfarlane et al. teach the production of butyrate from monosaccharide and disaccharide substrates broadly in the human colon, which differs from the instantly claimed invention only with respect to the fact that D-tagatose is not specifically cited; however, Zehner teaches that unabsorbable sugars such as D-tagatose are subject to fermentation in the human colon, which adequately bridges the nexus between the differences in the prior art and the invention  
20 as claimed.

      The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 25       1. Determining the scope and contents of the prior art.  
      2. Ascertaining the differences between the prior art and the claims at issue.  
      3. Resolving the level of ordinary skill in the pertinent art.  
30       4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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A *prima facie* case of obviousness is supported when the prior art alone would have appeared to suggest doing, at the time the invention was made, what the applicant has done.

5 The prior art cited supra has set forth that monosaccharides such as D-tagatose serve as a substrate for the production of Short Chain Fatty Acids such as butyrate and also allow for the growth of commensalistic indigenous flora such as Lactobacilli. Therefore, it would have been *prima facie* obvious to use D-tagatose or any other saccharide which may be positively  
10 fermented by indigenous microflora of the human large intestine in a method for inducing production of butyrate or stimulating the growth of lactobacilli and lactic acid bacteria.

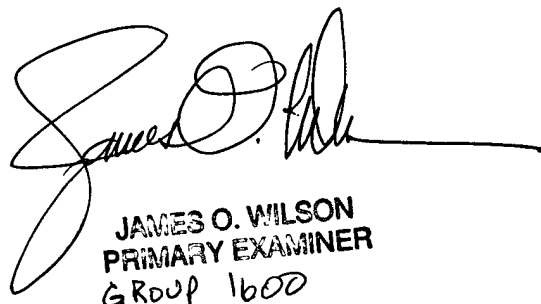
One of skill in the art would have been motivated to use D-tagatose as a substrate for inducing production of butyrate or  
15 stimulating the growth of lactobacilli and lactic acid bacteria as the prior art teaches that D-tagatose is not broken down until it traverses to the large intestine, enabling the growth of positive flora such as Lactobacilli and also allowing for the production of SCFA's, specifically butyrate. Moreover, one of  
20 skill in the art would have a reasonable expectation of success for the production of butyrate or the growth of Lactobacilli with not only D-tagatose, but any other mono or disaccharide which escapes digestion in the small intestine and has been indicated by the prior art as a substrate for commensalistic flora from  
25 which SCFA's such as butyrate are produced.

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Any inquiry concerning this communication or earlier  
communications from the examiner should be directed to Howard Owens  
5 whose telephone number is (703) 306-4538 . The examiner can normally be  
reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful,  
the Primary Examiner signing this action, James O. Wilson can be reached  
on (703) 308-4624 . The fax phone number for this Group is (703) 308-  
10 4556.

Any inquiry of a general nature or relating to the status of this  
application or proceeding should be directed to the Group receptionist  
whose telephone number is (703) 308-1235.



JAMES O. WILSON  
PRIMARY EXAMINER  
Group 1600